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From: Vodola2@aol.com
Sent: Wednesday, May 24, 2000 6:47 PM
To: DrugInfo@cder.fda.gov; ombudsma@oc.fda.gov
Subject: RU-486

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May 2000

President William Jefferson Clinton
The White House
1600 Pennsylvania Ave.
Washington, DC 20500

*copy to DIB
and
Today Sponge sheet*

Dear President Clinton,

As a person who cares about reproductive health of women, I am concerned about the ongoing multi-year delay in the Food and Drug Administration's (FDA) approval of RU-486 and the Today Sponge. These delays do not seem warranted whatsoever by science but are in fact motivated by politics. Your leadership is urgently needed now, before the end of your term.

On January 22, 1993, only three days into your first administration, you signed a presidential memorandum directing Donna Shalala, Secretary of Health and Human Services to determine whether the import ban on mifepristone (RU-486) was justified and to rescind the ban if there was no basis for it. At that signing you said:

"We must free science and medicine from the grasp of politics and give all Americans access to the very latest and best medical treatments... Here in the United States, RU-486 has been held hostage to politics. It is time to learn the truth about what the health and safety risks of the drug really are."

As a result of your actions, the ban was lifted and, after three years of study by the Food and Drug Administration, in July of 1996 RU-486 was found to be safe and effective. Since that time you have advocated to make it possible for American women to have access to this drug, which has been used safely by hundreds of thousands of women around the world. Your administration negotiated with Roussel Uclaf to donate the American patent rights to the Population Council. In 1998, you threatened to veto a spending bill for the Department of Agriculture because the bill contained a provision banning the Food and Drug Administration from testing and developing RU-486 and other drugs that chemically induce abortion.

I am also deeply concerned about the delay-upon-delay in the approval process for the Today Sponge, an important over-the-counter, female-controlled contraceptive. It appears the Sponge has already passed all safety tests but that the FDA has repeatedly re-scheduled inspection of the production facility. These delays can only be seen as a political decisions on the part of the FDA.

All Americans should have access to the most current and best medical treatments available. The women of America are best served when they have access to the greatest number of options to make the best reproductive health choices. This is sound medical policy, good public health, and the right thing to do for American women and their families.

We ask you to use the power of the presidency once again by calling upon the FDA to set and adhere to a strict and speedy timetable for approval of RU-486 and the Today Sponge. As the election draws nearer, we are afraid that abortion politics will continue to limit choices for U.S. women. Your influence can ensure that U.S. women will have access to these important medical advancements.

Thank you,

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